K132632

TORNIER

4 510(k) Summary

SEP 19 2013

510(K) Owner's Name:	Tornier Inc.
Address:	10801 Nesbitt Avenue South Bloomington, Minnesota 55437
Phone and Fax Numbers:	Phone: 952.426.7600 Fax: 952.426.7601
Name of Contact Person:	Janell A. Colley
Date Prepared:	August 19, 2013
Trade or Proprietary Name:	Tornier Insite FT Suture Anchor with Needles
Common or Usual Name:	Smooth or threaded metallic bone fixation fastener
Classification Name:	Product Code: MBI 21 CFR 888.3040
Legally Marketed Device to Which Your Firm Is Claiming Equivalence:	K110773 - Tornier Insite FT Suture Anchor, cleared 2 June 2011 K083268 - Tornier, Inc., Insite Suture Anchor, cleared 12 February 2009
Description of The Device:	The Tornier Insite FT Titanium Suture Anchor w/ Needles consists of a bone implant device intended for the fixation of soft tissue to bone. The device is a fully threaded titanium suture anchor preloaded on a disposable inserter assembly, attached USP size#2-0 or USP size #0 UHMWPE suture and comes with needles attached to the ends of the suture. The Tornier Insite FT Titanium Suture Anchor w/ Needles is used as a means for securing soft tissue to bone. The implant is individually packaged and sterilized though ethylene oxide (EO) using appropriate standard and guidelines
Intended Use of the Device:	The **Tornier Insite FT Suture Anchor** is intended for fixation of soft tissue to bone. The **Tornier Insite FT Suture Anchor** is intended for use in the following applications: **Shoulder:** Rotator Cuff, Bankart and SLAP lesion repair, Biceps tenodesis, Acromio-Clavicular separation and Deltoid repair, Capsular shift and Capsulolabral reconstruction. **Foot/Ankle:** Lateral and Medial stabilization, Achilles tendon and Metatarsal ligament repair, Hallux Valgus and Midfoot Reconstruction. **Knee:** Medial collateral and Lateral collateral ligament repair, Patellar tendon and Posterior oblique ligament repair, Illiotibial band tenodesis. **Hand/Wrist:** Scapholunate ligament, Radial collateral ligament and Ulnar collateral ligament reconstruction. **Elbow:** Biceps tendon reattachment, Tennis elbow repair, Ulnar and Radial collateral ligament reconstruction.
Technological Characteristics Compared To Predicate Device:	The technological characteristics (material, design, sizing, indications, sterilization, failure strength) of the Tornier Insite FT Ti Suture Anchor w/ Needles are substantially equivalent to the predicate devices.
Summary of the Nonclinical Tests Submitted:	Non-clinical laboratory testing was performed to evaluate the device performance per design requirements and risk analysis, including cyclic testing, mechanical insertion and pullout testing, driver torque testing, suture needle pull testing, and cadaveric laboratory simulated use testing. All tests met the pre-established acceptance criteria
Conclusions Drawn From the Nonclinical and Clinical Tests:	Based on risk analysis and acceptable results from testing, the Tornier Insite FT Suture Anchor with Needles was found to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Tornier, Incorporated
Ms. Janell Colley
Regulatory Affairs Manager
10801 Nesbitt Avenue South
Bloomington, Minnesota 55437

September 19, 2013

Re: K132632
Trade/Device Name: Tornier Insite FT Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: August 19, 2013
Received: August 22, 2013

Dear Ms. Colley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Elizabeth L. Frank -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TORNIER

3 **Statement of Indications for Use**

510(k) Number: ~~TBD~~ K132632

Device Name: **Tornier Insite FT Suture Anchor**

Indications for Use

The **Tornier Insite FT Suture Anchor** is intended for fixation of soft tissue to bone.

The **Tornier Insite FT Suture Anchor** is intended for use in the following applications:

1. **Shoulder:** Rotator Cuff, Bankart and SLAP lesion repair, Biceps tenodesis, Acromio-Clavicular separation and Deltoid repair, Capsular shift and Capsulolabral reconstruction.
2. **Foot/Ankle:** Lateral and Medial stabilization, Achilles tendon and Metatarsal ligament repair, Hallux Valgus and Midfoot Reconstruction.
3. **Knee:** Medial collateral and Lateral collateral ligament repair, Patellar tendon and Posterior oblique ligament repair, Illiotibial band tenodesis.
4. **Hand/Wrist:** Scapholunate ligament, Radial collateral ligament and Ulnar collateral ligament reconstruction.
5. **Elbow:** Biceps tendon reattachment, Tennis elbow repair, Ulnar and Radial collateral ligament reconstruction.

Prescription Use ___X___ AND/OR Over-The-Counter Use___

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

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